

**IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA**

CHARLESTON DIVISION

DIANNE M. BELLEW,

Plaintiff,

v.

CIVIL ACTION NO. 2:13-cv-22473

ETHICON, INC., et al.,

Defendants.

**MEMORANDUM OPINION AND ORDER
(Defendants' Motion for Partial Summary Judgment Dismissing Plaintiff's Punitive
Damages Claims with Prejudice)**

Pending before the court is the defendants' Motion for Partial Summary Judgment Dismissing Plaintiff's Punitive Damages Claims with Prejudice [Docket 120]. For the reasons stated below, the Motion is **DENIED**.

I. Background

This bellwether case resides in one of seven MDLs assigned to me by the Judicial Panel on Multidistrict Litigation concerning the use of transvaginal surgical mesh to treat pelvic organ prolapse ("POP") and stress urinary incontinence ("SUI"). In the seven MDLs, there are more than 67,000 cases currently pending, approximately 22,000 of which are in the Ethicon, Inc. MDL, MDL 2327. In this particular case, the plaintiff was surgically implanted with the Prolift Anterior Pelvic Floor Repair System ("Prolift"), a mesh product manufactured by Ethicon and Johnson & Johnson (collectively, "Ethicon" or "the defendants") to treat POP. (*See* Short Form

Compl. [Docket 1] ¶¶ 6, 8).¹ The plaintiff received her surgery in Arizona. (*Id.* ¶ 11). The plaintiff claims that as a result of implantation of the Prolift, she has experienced multiple complications, including mesh erosion, mesh contraction, inflammation, dyspareunia (pain during sexual intercourse), urinary incontinence, chronic pain, and recurring prolapse of organs. (Master Compl. ¶ 49). In addition, she had four subsequent operations to remove and revise the mesh. (Pl. Fact Sheet [Docket 206-1], at 7). The plaintiff alleges negligence, manufacturing defect, failure to warn, design defect, common law fraud, fraudulent concealment, constructive fraud, negligent misrepresentation, negligent infliction of emotional distress, breach of express warranty, breach of implied warranty, violation of consumer protection laws, gross negligence, unjust enrichment, and punitive damages. (Short Form Compl. [Docket 1] ¶ 13).²

Pursuant to the court's briefing schedule, Ethicon filed a Motion for Partial Summary Judgment Dismissing Plaintiff's Punitive Damages Claims with Prejudice [Docket 120] and its Memorandum in Support [Docket 123] ("Defs.' Mem.") on September 19, 2014. The plaintiff filed her Brief in Opposition [Docket 154] ("Pl.'s Resp.") on October 3, 2014. The matter is ripe for disposition.

II. Legal Standards

A. Partial Summary Judgment

A partial summary judgment "is merely a pretrial adjudication that certain issues shall be deemed established for the trial of the case." Fed. R. Civ. P. 56 advisory committee's note. A motion for partial summary judgment is governed by the same standard applied to consideration

¹ I have selected this case as a Prolift bellwether case in the Ethicon MDL. (*See* Pretrial Order # 98 [Docket 29], at 1).

² Since filing her short form complaint, the plaintiff has dropped several causes of action from her lawsuit. (*See* Pl.'s Opp. to Defs.' Mot. for Summ. J. [Docket 153], at 1 n.1 ("Ms. Bellew will not pursue any causes of action for manufacturing defect, breach of implied warranty, constructive fraud, unjust enrichment, negligent infliction of emotional distress, or 'strict liability—product defect' (except to the extent the latter encompasses design defect and failure to warn).")).

of a full motion for summary judgment. *See Pettengill v. United States*, 867 F. Supp. 380, 381 (E.D. Va. 1994) (citing *Gill v. Rollins Protective Servs. Co.*, 773 F.2d 592, 595 (4th Cir. 1985)). To obtain summary judgment, the moving party must show that there is no genuine issue as to any material fact and that the moving party is entitled to judgment as a matter of law. Fed. R. Civ. P. 56(a). In considering a motion for summary judgment, the court will not “weigh the evidence and determine the truth of the matter.” *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 249 (1986). Instead, the court will draw any permissible inference from the underlying facts in the light most favorable to the nonmoving party. *Matsushita Elec. Indus. Co. v. Zenith Radio Corp.*, 475 U.S. 574, 587–88 (1986).

Although the court will view all underlying facts and inferences in the light most favorable to the nonmoving party, the nonmoving party nonetheless must offer some “concrete evidence from which a reasonable juror could return a verdict in his [or her] favor[.]” *Anderson*, 477 U.S. at 256. Summary judgment is appropriate when the nonmoving party has the burden of proof on an essential element of his or her case and does not make, after adequate time for discovery, a showing sufficient to establish that element. *Celotex Corp. v. Catrett*, 477 U.S. 317, 322–23 (1986). The nonmoving party must satisfy this burden of proof by offering more than a mere “scintilla of evidence” in support of his or her position. *Anderson*, 477 U.S. at 252. Likewise, conclusory allegations or unsupported speculation, without more, are insufficient to preclude the granting of a summary judgment motion. *See Felty v. Graves Humphreys Co.*, 818 F.2d 1126, 1128 (4th Cir. 1987); *Ross v. Comm’ns Satellite Corp.*, 759 F.2d 355, 365 (4th Cir. 1985), *abrogated on other grounds*, *Price Waterhouse v. Hopkins*, 490 U.S. 228 (1989).

B. Choice of Law

Before determining whether summary judgment is appropriate, I must decide what law

applies to the plaintiff's punitive damages claims. "For cases that originate elsewhere and are directly filed into the MDL, I will follow the better-reasoned authority that applies the choice-of-law rules of the originating jurisdiction, which in our case is the state in which the plaintiff was implanted with the product." *Sanchez v. Boston Scientific Corp.*, 2:12-CV-05762, 2014 WL 202787, at *4 (S.D. W. Va. Jan. 17, 2014).

The choice-of-law issue here is almost identical to one I resolved previously in *Lewis, et al. v. Ethicon*, No. 2:12-CV-4301, 2014 WL 186869, (S.D.W. Va. Jan. 15, 2014), *rev'd in part sub nom.*, No. 2:12-CV-4301, 2014 WL 457551 (S.D. W. Va. Feb. 3, 2014). There, the plaintiff was implanted with pelvic mesh in Texas, a jurisdiction that follows the Restatement (Second) of Conflicts of Laws and relies on the most-significant-relationship test to resolve choice-of-law issues in tort. *Id.* at *2. Ethicon argued in *Lewis* that under the most-significant-relationship test, New Jersey substantive law applied to the plaintiffs' punitive damages claims. *Id.* at *9. "Although the plaintiffs expressly claim[ed] that they d[id] not concede that New Jersey's law applie[d], they appear[ed] to assume that it d[id], and they d[id] not assert that the law of any other state applie[d] to their punitive damages claim." *Id.* (internal quotation marks and citation omitted).

Here, Ms. Bellew was implanted with the Prolift device in Arizona. (Short Form Compl. [Docket 1] ¶¶ 8, 11). Had she not filed directly into the MDL, venue would have been proper in Arizona federal court. (*Id.* ¶ 5). Accordingly, I must turn to Arizona conflicts principles. *Klaxon Co. v. Stentor Elec. Mfg. Co.*, 313 U.S. 487, 496 (1941). Like Texas, Arizona follows the Restatement (Second) of Conflicts of Laws for issues concerning tort. *Bryant v. Silverman*, 703 P.2d 1190, 1191–93 (Ariz. 1985). As in *Lewis*, Ethicon contends here that New Jersey law applies to the plaintiff's punitive damages claims, (*see* Defs.' Mem. [Docket 123], at 7–8), and

the plaintiff implicitly accepts this to be so. (*See* Pl.’s Resp. [Docket 154], at 8–19 (framing arguments in terms of New Jersey law and declining to argue that another state’s law applies)). The Second Restatement also supports application of New Jersey law to the issue of punitive damages because the alleged misconduct took place at the defendants’ principal place of business in New Jersey. *See* Restatement (Second) of Conflict of Laws § 145 cmt. c (1971) (“If the primary purpose of the tort rule involved is to deter or punish misconduct, . . . the state where the conduct took place may be the state of dominant interest and thus that of most significant relationship.”); *Bryant*, 703 P.2d at 1194 (concluding that for punitive damages, the place of injury “is much more fortuitous than the place defendant selects as his place of incorporation and principal place of business or the place of misconduct,” and therefore, “the place of injury carries little weight in our selection of the applicable state law on punitive damages”). For these reasons, I **FIND** that New Jersey law applies to the plaintiff’s punitive damages claims.

III. Analysis

Having concluded that New Jersey law applies to the plaintiff’s claims for punitive damages, I turn to Ethicon’s arguments for partial summary judgment: federal law preempts certain of the plaintiff’s claims for punitive damages; the New Jersey Product Liabilities Act (“NJPLA”), N.J. Stat. Ann. § 2A:58C-1 *et seq.* (West 2014), precludes an award of punitive damages here; and there is no dispute over any material facts with respect to punitive damages and Ethicon is entitled to judgment as a matter of law. For the reasons below, I reject each of these contentions.

A. Federal Law Does Not Preempt the Plaintiff’s Claims for Punitive Damages

Ethicon maintains that certain of the plaintiff’s allegations “are preempted by federal law.” (*See* Defs.’ Mem. [Docket 123], at 9). I have analyzed this issue with respect to

compensatory damages in this case, concluding that “preemption is not warranted.” (Mem. Opinion & Order re: Def.’s Mot. for Partial Summ. J. Based on Preemption (“Order”) [Docket 280], at 12). Ethicon draws no distinction here between compensatory and punitive damages for the purposes of preemption analysis, and the reasoning set forth in the Order referenced above is broad enough to cover both substantive claims and punitive damages claims. (*See generally id.* (rejecting the preemption argument on the basis of Supreme Court precedent and FDA regulations on medical device clearance)). Accordingly, I defer to this Order and **FIND** that the plaintiff’s punitive damages claims with respect to the Prolift are not preempted by federal law.

B. The NJPLA Does Not Preclude the Plaintiff’s Claims for Punitive Damages

The NJPLA precludes awards of punitive damages when the device in question “was subject to premarket approval or licensure by the federal Food and Drug Administration . . . and was approved or licensed; or is generally recognized as safe and effective pursuant to conditions established by the federal Food and Drug Administration and applicable regulations.” N.J. Stat. Ann. § 2A:58C-5. Ethicon focuses its argument on the second prong, contending that the relevant 510(k) regulatory clearance history constitutes recognition by the FDA that the Prolift was “safe and effective.” (*See* Defs.’ Mem. [Docket 123], at 11–18).

Specifically, Ethicon argues that the FDA recognized the Prolift as safe and effective for the purposes of § 2A:58C-5 because the FDA granted 510(k) clearance of Prolift and its component materials. (*See id.* at 4–6, 11–14). I have already addressed and rejected these arguments. First, I concluded that 510(k) clearance says nothing about a medical device’s independent safety. (*See* Order [Docket 280], at 10 (“[T]he 510(k) process is focused on equivalence, not safety.” (quoting *Medtronic, Inc. v. Lohr*, 518 U.S. 470, 403 (1996)))). Second, it would be incorrect to consider individual component parts, rather than the device as a whole,

when applying FDA preemption. (*See id.* at 7 (“[A] device receiving 510(k) approval cannot be separated into its component parts to create express preemption.” (quoting *Lewis*, 991 F. Supp. 2d at 760))). I adopt these conclusions here.

Ethicon’s additional argument in reliance on an Ohio federal court decision is unpersuasive. Ethicon states that the Southern District of Ohio has “appl[ie]d O.R.C. §2307.80(c)—a statutory exception virtually identical to N.J.S.A. § 2A:58C-5—to preclude punitive damages where the medical device at issue was cleared through the 510(k) process.” (Defs.’ Mem. [Docket 123], at 16). Ethicon’s reading of the Ohio case, however, is incorrect. The Ohio court did not determine that 510(k) clearance precluded punitive damages and instead found that the plaintiff’s punitive damages claims survived summary judgment as a result of the defendant’s alleged failures to comply with certain 510(k) standards:

Under Ohio law, punitive damages are precluded if the device “was manufactured and labeled in relevant and material respects in accordance with the terms of an approval or license issued by the federal Food and Drug Administration under the ‘Federal Food, Drug, and Cosmetic Act.’” O.R.C. § 2307.80(C). . . .

Here, Plaintiff pleads that, in conflict with the requirements of the 510(k) approval process, the Articul/EZE ceramic femoral head was adulterated because the product failed to meet performance standards, that Defendant failed to establish and maintain current good manufacturing practice with respect to quality audits, quality testing, and process validation, and that as a result of Defendant’s failure to maintain such standards as required by the 510(k) approval process, the device failed and caused Plaintiff’s injuries. . . .

Accordingly, construing the complaint in the light most favorable to Plaintiff, the allegations set forth therein sufficiently state a claim for punitive damages.

Marcum v. DePuy Orthopedics, Inc., No. 1:12-CV-834, 2013 WL 1867010, at *6–7 (S.D. Ohio May 2, 2013) (emphasis added).

For the reasons herein, as well as the analysis set forth in my previous Order, I reject Ethicon's contention that the FDA has recognized the Prolift as safe and effective such that NJPLA preclusion is appropriate.

C. The Defendants Have Not Shown the Absence of a Dispute of Material Fact

Ethicon's final argument is that it has shown there is no dispute over any material fact regarding punitive damages and that Ethicon is entitled to judgment as a matter of law. To assess this contention, I must view the evidence in the light most favorable to the plaintiff and permit her any reasonable factual inferences. Under New Jersey law, punitive damages are appropriate "only if the plaintiff proves, by clear and convincing evidence, that the harm suffered was the result of the defendant's acts or omissions, and such acts or omissions were actuated by actual malice or accompanied by a wanton and willful disregard of persons who foreseeably might be harmed by those acts or omissions." N.J. Stat. Ann. § 2A:15-5.12. Below I consider a few of the plaintiff's factual assertions and the accompanying citations to the record, which, viewed in the light most favorable to the plaintiff, show that she has offered some concrete evidence, more than a mere scintilla, to support her claims for punitive damages under New Jersey law.

For instance, the plaintiff cites the deposition testimony of Ethicon employees for the proposition that Ethicon knew but failed to warn about severe risks associated with the Prolift. (*See* Pl.'s Resp. [Docket 154], at 15; Pl.'s Mem. in Supp. of Mot. for Partial Summ. J. on Failure to Warn & Proximate Causation ("Pl.'s Mem. on Failure to Warn") [Docket 113] ¶¶ 14–30). Furthermore, the plaintiff claims Ethicon never disclosed that, once implanted, the Prolift likely could not be fully removed. (*See* Pl.'s Resp. [Docket 154], at 17; Pl.'s Mem. on Failure to Warn [Docket 113] ¶¶ 17, 49–51 (citing Owens Dep. [Docket 112-3])). Despite multiple surgeries, doctors have not been able to fully remove Ms. Bellew's mesh, and she continues to experience

pain. (Pl.'s Resp. [Docket 154], at 17).

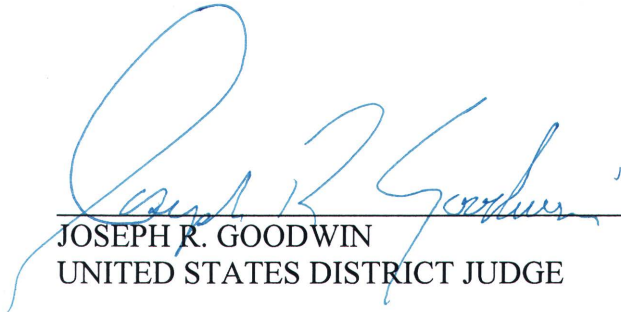
Viewing the factual assertions above in the light most favorable to the plaintiff, I conclude that a reasonable jury could find that Ethicon's acts or omissions with respect to the Prolift were, at a minimum, accompanied by a wanton or willful disregard of persons who foreseeably might be harmed. Genuine disputes of material fact with respect to punitive damages exist. Accordingly, I reject Ethicon's contention that the plaintiff's claims for punitive damages are insufficient as a matter of law.

IV. Conclusion

For the reasons stated above, Ethicon's Motion for Partial Summary Judgment Dismissing Plaintiff's Punitive Damages Claims with Prejudice [Docket 120] is **DENIED**.

The court **DIRECTS** the Clerk to send a copy of this Order to counsel of record and any unrepresented party.

ENTER: November 24, 2014



JOSEPH R. GOODWIN
UNITED STATES DISTRICT JUDGE